PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	26.11.2004
Applicant's or agent's file reference: JNR/PG4884	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/08152	23.07.2003	25.07.2002

Applicant
GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	HAEMAELAEINEN, E Tel. +49 89 2399-

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4884	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/08152	International filing date *(day/month/year)* 23.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.01.2004	26.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Azaïzia, M Telephone No. +49 89 2399-6960

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/08152

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-45 as originally filed

Claims, Numbers

1-23 as originally filed

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 23

   because:

   ☒ the said international application, or the said claims Nos. 23 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 23

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-22
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. For the purposes of international preliminary examination, a "use" claim of a form such as "use of a medicament dispenser device according to any of claims 1 to 22 for dispensing a combination medicament product" (see claim 23) is regarded as equivalent to a "method" claim of the form "**method for dispensing a combination medicament product** using a medicament dispenser device according to any of claims 1 to 22" (see the PCT Guidelines - as in force from 9 October 1998 - Section IV, Chapter III, 4.9). Therefore, independent claim 23 is considered to relate to a method for dispensing a combination medicament product in order to treat a patient, such a method being considered as a method for treatment of the human body by therapy.

   Method claim 23 relates therefore to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:
   D1: US-A-5 437 267 (1995-08-01)
   D4: WO-A-03 061744 (2003-07-31)

3. Although claims 1 and 3 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

   Hence, claims 1 and 3 do not meet the requirements of Article 6 PCT.

3.1 Nevertheless, claim 3 refers to **the** first medicament dispenser and **the** at least one further medicament dispenser, which are both firstly defined in independent claim 1. Claim 3 appears therefore to define only a preferred embodiment of the invention defined by independent claim 1, and should therefore have been drafted as dependent on claim 1.

For the purpose of this report, claim 3 has been considered as dependent on claim 1.

4. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. column 5, lines 24-38, fig.4A) a unitary medicament dispenser device from which the subject-matter of independent claim 1 differs in that the first medicament dispenser device is different in type to the at least one further medicament dispenser.

The device according to claim 1 enables convenient, combined delivery of the components of a combination medicament product to a patient, where a particular component medicament of the combination product is suited to delivery by one particular type of inhaler device (e.g an MDI device), whereas the other component medicament of that combination product is suited to delivery by a different type of inhaler device (e.g an DPI device).
In addition, using a single inhaler device according to claim 1 can potentially reduce the complexity, timescale and cost of development process for a particular combination medicament product because it enables the optimum delivery vehicle to be selected for each particular medicament component of the combination medicament product.

This distinguishing feature of the present invention is novel and cannot be derived in an obvious manner from the cited documents. Independent claim 1 meets therefore the requirements of the PCT with respect to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

4.1 Claims 2-22 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

5. The subject-matter of claims 1-22 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT).

------ Certain documents cited ------

6. The document WO-A-03 061744 (D4) was cited by virtue of Rule 64.3 PCT. The following data (Rule 70.10 PCT) concerning this document are given:

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 03/061744	31.07.2003	22.01.2003	25.01.2002 25.07.2002

------ Certain defects in the international application ------

7. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

8. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

9. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

------ Certain observations on the international application ------

10. In the definition of its dependency, claim 8 refers to itself. For the purpose of this report, claim 8 has been considered as dependent on any of claims 3 to 7.

11. Dependent claims 8, 11 and 12 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. These claims refer indeed to **the multi-dose dry powder inhaler (MDPI)** (see claim 8) and/or to **the metered dose inhaler (MDI)** (see claims 11 and 12), which are for example not definitely claimed in independent claim 3, so these claims lack clarity (Article 6 PCT) when depending on claim 3 for example.

12. It is pointed out that an invention entitles the applicant to a unique and single patent. Nevertheless, it seems that the applicant has filed two different applications for the same invention: an overlapping in the subject-matter claimed in the current application WO2003/EP08152 and the application WO2003/EP08151 exists (see for example claim 1 of WO2003/EP08152 and claim 7 of WO2003/EP08151). The applicant may be required in the national phase to choose for each application a different invention to continue with for the procedure or to choose which one of those applications he wishes to proceed to grant (see the PCT Guidelines - as in force from 9 October 1998 - Section IV, Chapter IV, 6.3).